

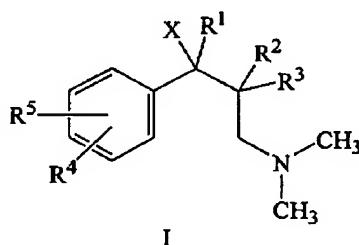
AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1.-43. (Canceled)

44. (New) A pharmaceutical salt of a salt-forming pharmaceutical active compound and at least one salt-forming sugar substitute, wherein the salt-forming pharmaceutical active compound is a salt-forming 1-phenyl-3-dimethylaminopropane compound of the formula I:



in which

X represents OH, F, Cl, H or an OCOR<sup>6</sup> group;

R<sup>1</sup> represents a C<sub>1-4</sub>-alkyl group;

R<sup>2</sup> represents H or a C<sub>1-4</sub>-alkyl group; and

R<sup>3</sup> represents H or a straight-chain C<sub>1-4</sub>-alkyl group;

or R<sup>2</sup> and R<sup>3</sup> together with the carbon atom to which they are attached form a C<sub>4-7</sub>-cycloalkyl radical; and

R<sup>5</sup> represents H; and

USSN 10/647,882

Amendment under 37 CFR § 1.111 filed on October 23, 2008

$R^4$  represents meta-O-Z where Z is H,  $C_{1-3}$ -alkyl,  $PO(O-C_{1-4}$ -alkyl)<sub>2</sub>,  $CO(OC_{1-5}$ -alkyl),  $CONH-C_6H_4-(C_{1-3}$ -alkyl),  $CO-C_6H_4-R^7$ , where  $R^7$  is ortho-OCOC<sub>1-3</sub>-alkyl or meta- or para- $CH_2N(R^8)_2$  where  $R^8$  is  $C_{1-4}$ -alkyl or 4-morpholino, or  $R^4$  is meta-S- $C_{1-3}$ -alkyl, meta-Cl, meta-F, meta- $CR^9R^{10}R^{11}$  where  $R^9$ ,  $R^{10}$ ,  $R^{11}$  are H or F, ortho-OH, ortho-O- $C_{2-3}$ -alkyl, para-F or para- $CR^9R^{10}R^{11}$  where  $R^9$ ,  $R^{10}$ ,  $R^{11}$  are H or F;

or  $R^5$  represents para-Cl, -F, -OH or -O- $C_{1-3}$ -alkyl; and

$R^4$  represents meta-Cl, -F, -OH or -O- $C_{1-3}$ -alkyl;

or  $R^4$  and  $R^5$  together are 3,4-OCH=CH- or 3,4-OCH=CHO-; and

$R^6$  represents  $C_{1-3}$ -alkyl;

said salt-forming pharmaceutical active compound optionally being, where possible, in the form of a racemic mixture, in the form of a diastereomerically pure enantiomer, or in the form of a mixture of enantiomers, wherein in such mixture of enantiomers, the enantiomers are present in different amounts.

45. (New) The pharmaceutical salt of claim 44, which exhibits a solubility in water of  $\leq 250$  mg/ml.

46. (New) The pharmaceutical salt of claim 45, which exhibits a solubility in water of  $\leq 200$  mg/ml.

47. (New) The pharmaceutical salt of claim 46, which exhibits a solubility in water of  $\leq 150$  mg/ml.

48. (New) The pharmaceutical salt of claim 47, which exhibits a solubility in water of  $\leq 100$  mg/ml.

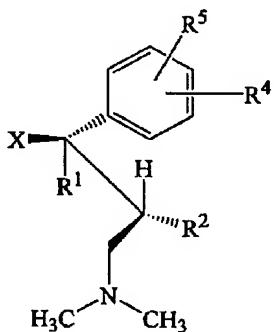
49. (New) The pharmaceutical salt of claim 44, wherein the at least one salt-forming

sugar substitute is selected from the group consisting of saccharin, cyclamate and acesulfam.

50. (New) The pharmaceutical salt of claim 49, wherein the at least one salt-forming sugar substitute is saccharin.

51. (New) The pharmaceutical salt of claim 44, wherein X is OH, F, Cl or H; R<sup>1</sup> is a C<sub>1-4</sub>-alkyl group; R<sup>2</sup> is H or CH<sub>3</sub>; and R<sup>3</sup> is H or CH<sub>3</sub>; and if R<sup>5</sup> is H, R<sup>4</sup> is meta-O-C<sub>1-3</sub>-alkyl, meta-OH, meta-S-C<sub>1-3</sub>-alkyl, meta-F, meta-Cl, meta-CH<sub>3</sub>, meta-CF<sub>2</sub>H, meta-CF<sub>3</sub> or para-CF<sub>3</sub>; or if R<sup>5</sup> is a para-Cl or -F, R<sup>4</sup> is meta-Cl or -F; or R<sup>4</sup> and R<sup>5</sup> together are 3,4-OCH=CH-.

52. (New) The pharmaceutical salt of claim 44, wherein R<sup>2</sup> and R<sup>3</sup> are different from one another; and the salt-forming pharmaceutical active compound of formula I is present in the form of a diastereomer of the formula Ia:



Ia.

53. (New) The pharmaceutical salt of claim 44, wherein the salt-forming pharmaceutical active compound is selected from the group consisting of:

(1RS,2RS)-3-(3-dimethylamino-1-hydroxy-1,2-di-methylpropyl)phenol;

(-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol;

(+)-(1S,2S)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol;

(2RS,3RS)-1-dimethylamino-3-(3-methoxyphenyl)-2-methylpentan-3-ol;  
(-)-(1S,2S)-3-(3-dimethylamino-1-ethyl-1-fluoro-2-methylpropyl)phenol;  
(+)-(1R,2R)-3-(3-dimethylamino-1-hydroxy-1,2-dimethylpropyl)phenol;  
(+)-(2R,3R)-1-dimethylamino-3-(3-methoxyphenyl)-2-methylpentan-3-ol; and  
(-)-(2S,3S)-1-dimethylamino-3-(3-methoxyphenyl)-2-methylpentan-3-ol.

54. (New) The pharmaceutical salt of claim 53, wherein the salt-forming pharmaceutical active compound is selected from the group consisting of:

(-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol; and  
(+)-(1S,2S)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol.

55. (New) The pharmaceutical salt of claim 54, wherein the salt-forming pharmaceutical active compound is (-)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol.

56. (New) A pharmaceutical composition comprising a therapeutically effective amount of the pharmaceutical salt according to claim 44 and optionally one or more physiologically tolerable excipients.

57. (New) The pharmaceutical composition of claim 56, which is in a form selected from the group consisting of gels, chewing gums, juices, sprays, tablets, chewable tablets, coated tablets, powders, optionally filled into capsules, and easily reconstitutable dry preparations.

58. (New) The pharmaceutical composition of claim 57, which is in a form selected from the group consisting of tablets not intended to be chewed.

59. (New) The pharmaceutical composition of claim 55, which is in multiparticulate form.

60. (New) The pharmaceutical composition of claim 59, wherein the multiparticulate

form is selected from the group consisting of microtablets, microcapsules, granules, active compound crystals and pellets.

61. (New) The pharmaceutical composition of claim 60, wherein the multiparticulate form is selected from the group consisting of microtablets, granules and pellets, optionally filled into capsules or compressed to give tablets.

62. (New) The pharmaceutical composition of claim 55, wherein the pharmaceutical salt is at least partially in delayed-release form.

63. (New) The pharmaceutical composition of claim 62, wherein the pharmaceutical salt is at least partially within a release-delaying coating, embedded in a release-delaying matrix, or bound to an ion-exchange resin.

64. (New) The pharmaceutical composition of claim 63, wherein the pharmaceutical salt is at least partially within a release-delaying coating, and the release-delaying coating is based on a water-insoluble, optionally modified natural or synthetic polymer, optionally in combination with a customary plasticizer, or on a natural, semisynthetic or synthetic wax or fat or fatty alcohol or a mixture of at least two of these components.

65. (New) The pharmaceutical composition of claim 63, wherein the pharmaceutical salt is at least partially embedded in a release-delaying matrix, and the release-delaying matrix is based on a hydrophilic matrix material.

66. (New) The pharmaceutical composition of claim 65, wherein the hydrophilic matrix material is a hydrophilic polymer.

67. (New) The pharmaceutical composition of claim 66, wherein the hydrophilic polymer is selected from the group consisting of cellulose ethers, cellulose esters, acrylic resins and mixtures thereof.

68. (New) The pharmaceutical composition of claim 67, wherein the hydrophilic polymer is selected from the group consisting of ethylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxymethylcellulose, poly(meth)acrylic acid and the salts, amides

USSN 10/647,882

6

Amendment under 37 CFR § 1.111 filed on October 23, 2008

and/or esters thereof.

69. (New) The pharmaceutical composition of claim 63, wherein the pharmaceutical salt is at least partially embedded in a release-delays matrix, and the release-delays matrix is based on a hydrophobic matrix material.

70. (New) The pharmaceutical composition of claim 69, wherein the hydrophobic matrix material is a hydrophobic polymer.

71. (New) The pharmaceutical composition of claim 70, wherein the hydrophobic polymer is selected from the group consisting of waxes, fats, long-chain fatty acids, fatty alcohols, esters and ethers thereof, and mixtures thereof.

72. (New) The pharmaceutical composition of claim 71, wherein the hydrophobic polymer is selected from the group consisting of mono- or diglycerides of C<sub>12</sub>-C<sub>30</sub> fatty acids, C<sub>12</sub>-C<sub>30</sub>-fatty alcohols, waxes and mixtures thereof.

73. (New) The pharmaceutical composition of claim 56, which is in a form having a protective coating.

74. (New) The pharmaceutical composition of claim 73, wherein the protective coating is an enteric protective coating.

75. (New) A method for controlling pain comprising administering to a patient in need thereof a pain-controlling effective amount of the pharmaceutical salt of claim 44.

76. (New) A method for controlling urinary incontinence comprising administering to a patient in need thereof a urinary incontinence-controlling effective amount of the pharmaceutical salt of claim 44.

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

USSN 10/647,882  
Amendment under 37 CFR § 1.111 filed on October 23, 2008